

THE HONORABLE BARBARA J. ROTHSTEIN

03-CV-03289-CMP

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AT SEATTLE
CLERK U.S. DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
DEPUTY

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

IN RE Phenylpropanolamine (PPA) Products
Liability Litigation

CV 03-3289
MDL Docket No. 1407

This document relates to Hicks et al. v. Bayer, et al.
David Harris
CO3-2492
CV#

COMPLAINT OF
DAVID HARRIS

Re: CMO No. 15

AMENDED COMPLAINT¹

COMES NOW, Plaintiff, David Harris² by and through counsel, and files this Complaint against Defendant Smith-Kline Beechum ("SKB" or "Defendant"), and would show unto the Court the following:

NATURE OF ACTION

1. This product liability, negligence, and breach of warranty action arises out of the injuries Plaintiff sustained after ingesting BC Powder ("BC Powder") manufactured by SKB. SKB knew, or should have known, that BC Powder, and other products containing

¹ Pursuant to Case Management Order No. 15 concerning severance of multiple plaintiff cases in MDL 1407, Plaintiff hereby adopts his original complaint.

² Plaintiff originally erroneously sued Bayer Corporation.

Complaint of David Harris
(MDL Docket No. 1407)

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Phenylpropanolamine ("PPA") would cause serious injury, including death, to many of the millions of persons to whom they marketed and to whom they distributed BC Powder, and other products containing PPA. Only after the Food and Drug Administration reported the dangers associated with PPA did Defendant remove the product from the marketplace.

PARTIES³

2. Plaintiff David Harris is an adult resident citizen of Alabama. His ingestion of BC Powder proximately caused her injuries complained of herein.

3. Defendant Smith-Kline Beecham is a foreign corporation authorized to do business in Mississippi. Smith-Kline may be served with process on its registered agent Corporation Service Company at 506 S. President Street, Jackson, Mississippi 39201. At all relevant times herein, Smith-Kline was in the business of manufacturing, distributing, and promoting products containing PPA. Smith-Kline does business in this state, this county, and this judicial district, and at all relevant times hereto, marketed, promoted, warranted, and sold their products containing PPA in this State, in interstate commerce and throughout the United States.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction pursuant to Miss. Code Ann. § 11-7-13 (1972) and Miss. Code Ann. § 9-7-81.

5. Bayer is subject to the *in personam* jurisdiction of this Court as it is qualified to

³The allegations in the "Parties" and "Jurisdiction and Venue" sections were in Plaintiff's original complaint. Pursuant to CMO 15 Paragraph 1-A, these allegations remain unchanged and only the information required by CMO 15 has been added to the Complaint.

do business and is doing business in the State of Mississippi, and has a registered agent for process in Mississippi.

6. Smith-Kline is subject to the *in personam* jurisdiction of this Court as it is doing business in the State of Mississippi.

7. The cause of action described herein occurred and accrued in whole or in part in the First Judicial District of Hinds County, Mississippi. Therefore, this Court is the proper venue for this case pursuant to Miss. Code Ann. § 11-11-3.

8. Plaintiff brings this complaint solely under state law and not under federal law, and specifically not under the United States Constitution, or any of its amendments, or under any other federal statute, law, rule, or regulation. Plaintiff believes and alleges that causes of action exist against Defendant pursuant to the state-law claims described herein. If this Court or the appellate courts of Mississippi were to rule that Plaintiff has no cause of action under state law for the conduct set out herein, then Plaintiff simply does not have any remedy, because Plaintiff expressly waives and hereby disavows any claim for any relief whatsoever under any federal laws or any federal question concerning the allegations of this complaint, whether said allegations are pled or not.

FACTS

9. At all relevant times herein, Smith-Kline was a designer, manufacturer, advertiser, distributor, and seller of non-prescription, over-the-counter pharmaceutical products including cold, flu and allergy remedy products, which contained PPA as an active ingredient, including: Contac (hereinafter "PPA Products"). Smith-Kline purposefully and regularly distributed,

marketed, advertised, and sold the PPA Products in the State of Mississippi.

10. Based upon Smith Kline's promotions, marketing, advertisements, and other representations, Plaintiff purchased BC Powder believing the product was safe for him to ingest. However, unbeknownst to Plaintiff, Smith Kline's product was not safe as marketed and distributed, because it contained PPA as an active ingredient, Smith Kline failed to warn of the dangers associated with ingestion of PPA, and Smith Kline knew of active ingredients which were effective and a safer alternative and failed to replace PPA with said alternative.

11. PPA is a sympathomimetic drug closely related to amphetamines. It has been known in the medical and scientific communities for decades to cause life-threatening and/or fatal adverse effects to the cardiovascular and neurological systems. While general medical practitioners may not have had detailed knowledge of the similarities between PPA and amphetamines, manufacturers such as Bayer had such knowledge, or in light of reasonably available information, should have known, and thus knew of PPA's risks.

12. PPA is a vaso-constrictor, causing the constriction of blood vessels. This process raises blood pressure and causes hypertension. When blood pressure is raised to a critical level, and there is an increased myocardial oxygen demand, heart attacks and/or cardiac arrhythmia can result, as well as hemorrhagic strokes due to the increased intra-vascular pressure.

13. For at least two decades, Smith Kline was aware or should have been aware of the numerous scientific journal articles, as well as incident reports, textbooks, and other reports of serious life-threatening effects from human consumption of PPA, including stroke, seizure, heart attack, arrhythmias, psychosis and death.

14. Despite these serious and potentially fatal reactions, Smith Kline failed to warn

the general public, including Plaintiff, of the risks involved in ingesting PPA. While Smith Kline knew of its harmful effects, the general medical practitioners in the United States have not been fully informed of the significance of the risks of PPA ingestion.

15. At all relevant times, Smith Kline was a member of the Non-Prescription Drug Manufacturers Association (hereinafter referred to as "NDMA"; the NDMA is currently known as the Consumer Healthcare Products Association). Over the past two decades, Smith Kline, as a member of the NDMA, upon information and belief, undoubtedly knew of and participated in numerous communications and discussions directly related to the safety and known adverse effects of products containing PPA.

16. Members of the NDMA (including Smith Kline) and the NDMA's PPA Task Force had actual knowledge of the scientific community's concerns about PPA and of the numerous articles and reports evidencing the association between PPA and strokes, arrhythmia, heart attack, and death.

17. In 1994, members of the NDMA and the PPA Task Force had direct knowledge of at least one manufacturer and distributor (Thompson Medical Company) of over-the-counter, non-prescription drugs containing PPA that reported several life-threatening reactions to PPA and voluntarily added "black box" warning labels to its products which contained PPA. Such labels warned that: "There have been reports that stroke, seizure, heart attacks, arrhythmias, psychosis, and death might be associated with the ingestion of Phenylpropanolamine." Despite the feasibility and ease with which Smith Kline could have warned consumers about the dangers of its PPA Products, Smith Kline failed to do so, and the consumers who purchased and/or ingested Smith Kline's PPA products were never so warned or informed of these health dangers.

18. Smith Kline represented or impliedly represented that its PPA Products were safe and did not pose a risk of stroke, seizure, heart attacks, arrhythmias, psychosis, and death.

19. The NDMA and the industry of which Smith Kline is a member, reviewed medical and scientific literature regarding products containing active ingredients such as PPA and participated in discussions concerning the safety of PPA Products, such as those manufactured, sold and distributed by Smith Kline and the industry.

20. Smith Kline and other members of NDMA, directly or indirectly, participated in the funding of purported studies on the safety of PPA, when they knew the inaccuracies and inadequacies of said studies.

21. Smith Kline in concert with other over-the-counter non-prescription drug manufacturers, thwarted the FDA's attempts to accurately and completely conduct full fact-finding studies on the safety of PPA.

22. Pharmaceutical companies, such as Smith Kline have a professional and ethical duty to inform and warn the public, especially those purchasing their products, of known adverse and dangerous side effects associated with their products or active ingredients in their products.

23. Life-threatening adverse effects related to PPA leading to hospitalization and/or death have been well documented and known to pharmaceutical companies, including Smith Kline, for decades. These life-threatening events have been documented through FDA warning/sentinel events systems, showing a large number of such events related to PPA. Several life-threatening PPA injuries have been reported in Clin-Alert and other medical reports. However, Plaintiff and other consumers had no occasion to know about these reports.

24. PPA manufacturer-sponsored research efforts on safety, of which Smith Kline

either participated in and/or sponsored, lacked validity because the studies failed to systematically study the arrhythmogenic potential and known cardiac effects of PPA, or, until just before products containing PPA were withdrawn from the market, the potential neurological impact of PPA ingestion. Smith Kline failed to perform such studies despite the feasibility and compelling medical justification to do so.

25. Smith Kline's PPA Products were intended to function as over-the-counter cold, flu and allergy tablets, capsules and liquid products, and were designed, manufactured, marketed, advertised, distributed, and sold by Smith Kline as such. However, the PPA Products were not sufficiently or properly tested prior to being marketed to the public or at any time while being marketed to the public. Testing of the PPA Product's effects on the central nervous system or cardiovascular system was not performed over a reasonable period of time during the distribution and sale of the PPA Products to the public. Nevertheless, Smith Kline represented the PPA Products to be pharmaceutically tested and safe for consumption.

26. Smith Kline has concealed material facts, including the serious risks associated with ingesting PPA, from Plaintiff in product packaging, labeling, advertising, promotional campaigns and materials, among other ways, regarding the safety and use of products containing PPA.

27. Smith Kline concealed, omitted, or minimized the side effects of PPA, or provided misinformation about adverse reactions and potential harms from PPA, and succeeded in persuading consumers to purchase and ingest their PPA Products, despite the lack of safety and the risk of adverse medical reactions, including hemorrhagic stroke and other adverse neurological and cardiac effects.

28. Plaintiff ingested Smith Kline's BC Powder on or about June 1996. He suffered a stroke within 2 to 3 days of ingestion. Plaintiff's stroke and resultant damages are causally related to his ingestion of BC Powder.

**COUNT ONE
STRICT LIABILITY**

29. Plaintiff adopts by reference the preceding paragraphs.

30. At the time the BC Powder left the control Defendant, the BC Powder was defective because it failed to contain adequate warnings or instructions concerning the dangers that an ordinary user or consumer would not realize, but which were known or should have been known to Defendant.

31. At the time the BC Powder left the control of Defendant, the BC Powder product was designed in a defective manner. The BC Powder failed to function as expected, and there existed a feasible design alternative that would have, to a reasonable probability, prevented the harm to Plaintiff.

32. These defective conditions rendered the BC Powder unreasonably dangerous to the user or consumer.

33. The defective and unreasonably dangerous conditions of the BC Powder proximately caused the damages and injuries sustained by Plaintiff.

34. Defendant placed the defective and unreasonably dangerous BC Powder into the stream of commerce and proximately caused the damages and injuries sustained by Plaintiff.

35. As a result of Defendant's conduct as described herein, Plaintiff suffered damage entitling Plaintiff to compensatory damages. Further, Defendant's actions constitute gross

negligence and willful and wanton conduct, entitling Plaintiff to an award of punitive damages.

**COUNT TWO
NEGLIGENCE**

36. Plaintiff adopts by reference the preceding paragraphs.

37. Smith Kline owed a duty to Plaintiff and the public to design, manufacture, and sell its products in a condition that was reasonably safe for all of its intended and foreseeable uses. Smith Kline failed to design and manufacture the BC Powder in a reasonably safe manner for its intended and foreseeable uses and this failure constitutes negligence, which proximately caused Plaintiff's injuries

38. Defendant had a duty to warn Plaintiff and the public of the inherent dangers associated with the foreseeable use of the BC Powder. Defendant failed to adequately warn of the inherent dangers associated with the foreseeable uses of the BC Powder and this failure constituted negligence which proximately caused Plaintiff's injuries.

39. Smith Kline had a duty, but failed to adequately warn of serious injury and/or illness, including, but not limited to, stroke, seizure, heart attacks, arrhythmias, psychosis, death and other adverse medical conditions, posed by the ingestion of PPA. The warnings given by Smith Kline did not accurately reflect the risks, incidence, symptoms, scope, or severity of such injuries and/or illnesses. This failure constituted negligence, which proximately caused Plaintiff's injuries.

40. Smith Kline had a duty, but failed to perform adequate testing concerning the safety of PPA in that adequate testing would have shown that PPA posed and poses a serious risk of serious injury and/or illness including, but not limited to stroke, seizure, heart attacks,

arrhythmias, psychosis, death, and other adverse medical conditions. This failure constituted negligence, which proximately caused Plaintiff's injuries.

41. After Smith Kline knew or should have known of the risk posed by the use of PPA of serious injury and/or illness, including but not limited to stroke, seizure, heart attacks, arrhythmias, psychosis, death and other adverse medical conditions, Smith Kline had a duty, but failed, to provide adequate warnings to consumers about the products. This failure constituted negligence, which proximately caused Plaintiff's injuries.

42. Smith Kline had a duty, but failed, to timely and promptly recall or remove the BC Powder from over-the-counter availability when it knew or should have known of the hazards and adverse effects associated with the normal use of BC Powder. This failure constituted negligence, which proximately caused Plaintiff's injuries.

43. Smith Kline, once it knew or should have known, of the defective condition of the BC Powder, owed Plaintiff and the public a duty to redesign their products immediately. Smith Kline failed to redesign the BC Powder prior to Plaintiff's purchase of the BC Powder, and this failure constituted negligence, which proximately caused Plaintiff's injuries.

44. As a result of Defendant's negligence as described herein, Plaintiff suffered damage entitling Plaintiff to compensatory damages. Further, Defendant's actions constitute gross negligence and willful and wanton conduct entitling Plaintiff to an award of punitive damages.

**COUNT THREE
BREACH OF IMPLIED WARRANTY**

45. Plaintiff adopts by reference the preceding paragraphs.

46. Defendant violated Miss. Code Ann. § 75-2-315 and related statutes in that the BC Powder failed to perform as represented and were not fit for the particular purpose for which Plaintiff purchased the BC Powder.

47. At the time Defendant marketed, sold and distributed the BC Powder for use by Plaintiff, Defendant knew of the particular purpose and use for which the BC Powder was intended and warranted the product to be of merchantable quality and safe and fit for such use.

48. Plaintiff reasonably relied upon the skill and judgment of Defendant regarding whether the BC Powder was of merchantable quality and safe and fit for its intended purpose.

49. The BC Powder was not of merchantable quality or safe or fit for the intended use or purpose because the product was unreasonably dangerous and unfit for the ordinary purpose for which it was intended as described above.

50. As a result of Smith Kline's breach of the warranties described herein, Plaintiff suffered damages entitling Plaintiff to compensatory damages. Further, Defendant's action constitutes gross negligence and willful and wanton conduct, entitling Plaintiff to an award of punitive damages.

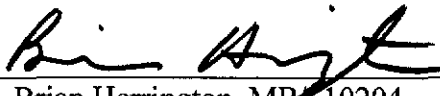
WHEREFORE, PREMISES CONSIDERED, Plaintiff demands judgment against Defendant, for the following relief:

- a. compensatory damages in an amount to be proven at trial;
- b. punitive damages in an amount to be proven at trial;
- c. all relief afforded by Miss. Code Ann. § 11-7-13 (1972);
- d. attorneys' fees, costs, and expenses; and
- e. any other relief that the Court deems equitable and proper.

This the 2nd day of October, 2003.

Respectfully submitted,

PLAINTIFF, DAVID HARRIS

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CERTIFICATE OF SERVICE

I hereby certify that t true and correct copy of the foregoing has been served this day via

United States Mail, postage prepaid, upon the following:

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ATTORNEY FOR SMITHKLINE BEECHAM

This the 2nd day of October, 2003.



Brian Herrington